Complete Summary

GUIDELINE TITLE

Guidelines for lumbar fusion (arthrodesis).

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Guidelines for lumbar fusion (arthrodesis). Olympia (WA): Washington State Department of Labor and Industries; 2002 Aug. 5 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Low back pain and associated symptoms

Note: Spinal fractures or dislocations, spinal infection, or spinal deformity (e.g., degenerative scoliosis) are not applicable in this guideline.

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Neurological Surgery
Neurology
Orthopedic Surgery
Physical Medicine and Rehabilitation

INTENDED USERS

Health Care Providers
Health Plans
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

- To serve as an instructional aid for physicians when treating injured workers who present with low back pain and associated symptoms that have developed in the context of routine work activities, and who have no evidence of spinal fracture
- To provide utilization review nurses with the information necessary to make recommendations about the medical necessity and clinical appropriateness of spinal fusions

TARGET POPULATION

Injured workers who present with low back pain and associated symptoms that have developed in the context of routine work activity, and who have no evidence of spinal fracture.

Note: These guidelines do not apply to requests for fusion to treat patients with a spinal fracture or dislocation, spinal infection, or spinal deformity (e.g., one related to degenerative scoliosis).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Initial treatment
    - Conservative therapy for low back pain, which predominantly emphasizes physical reconditioning
2. Surgical assessment for lumbar fusion
    - Detailed medical history including prior spinal surgeries (laminectomy, discectomy, or other decompressive procedure) and contraindications to surgery
    - Physical examination including checks for scoliosis and lumbar instability, pain assessment, neurological assessment
    - X-rays (flexion/extension views [L3-4, L4-5, L5-S1])
    - Magnetic resonance imaging (MRI) or computed tomography (CT) with or without myelography
    - Post-laminectomy structural study if available
    - Neurosurgical examination
    - Peer surgeon consult (if requested)
3. Prior to lumbar fusion surgery request
    - Clinical psychological or psychiatric assessment of all patients who meet the criteria for surgery and have been receiving time-loss compensation benefits
    - Patient education regarding procedure and prognosis
4. Post surgical follow-up
    - If pain is still present six months post surgery:
        - Neurological examination
        - Thin slice CT scan

    - Repeat x-rays
- Assign impairment rating
    - Permanent partial disability (PPD) assessment

MAJOR OUTCOMES CONSIDERED

- Pain and degree of functional recovery after lumbar fusion
- Rate of reoperation

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of the U.S. National Library of Medicine's Medline database to identify data related to the injured worker population.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus development has generally taken place between the permanent members of the subcommittee (orthopedic surgeon, physiatrist, occupational medicine physician, neurologist, neurosurgeon) and ad hoc invited physicians who are clinical experts in the topic to be addressed. One hallmark of this discussion is that, since few of the guidelines being discussed have a scientific basis, disagreement on specific points is common. Following the initial meeting on each guideline, subsequent meetings are only attended by permanent members unless information gathering from invited physicians is not complete.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following input from community-based practicing physicians, the guideline was further refined.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

I. Conservative care (consisting of all the following) should be tried first.
   A. The patient should have at least three months of conservative therapy for low back pain, which predominantly emphasizes physical reconditioning.
   B. The surgeon requesting the lumbar fusion should have personally evaluated the patient on at least two occasions prior to requesting the fusion.

      Exception: If the patient has a progressive neurological deficit, both conditions above can be waived.

II. If conservative care has failed to relieve symptoms and the patient has had no prior surgery, lumbar fusion should be considered only if the patient has one or more of the following:
   A. Mechanical (non-radicular) low back pain with instability

      Instability of the lumbar segment is defined as at least 4 mm of anterior/posterior translation at L3-4 and L4-5, or 5 mm of translation

at L5-S1 or 11 degrees greater end plate angular change at a single level, compared to an adjacent level. Adequate flexion/extension views should be taken utilizing techniques that minimize the potential contribution of hip motion to perceived lumbar flexion or extension.

Note: Only single level fusions will be approved for patients with no prior spinal surgery.

B. Spondylolisthesis exists with one or more of the following:
   1. Objective signs/symptoms of neurogenic claudication OR
   2. Objective signs/symptoms of unilateral or bilateral radiculopathy, which are corroborated by neurologic examination and by magnetic resonance imaging (MRI) or computed tomography (CT) (with or without myelography) OR
   3. Instability of the lumbar segment as defined above.

III. If conservative care has failed to relieve symptoms and the patient has had a prior laminectomy, discectomy, or other decompressive procedure at the same level, lumbar fusion should be considered only if the patient has one or more of the following:
   A. Mechanical (non-radicular) low back pain with instability (as defined above) at the same or adjacent levels OR
   B. Mechanical (non-radicular) low back pain with pseudospondylolisthesis, rotational deformity, or other condition leading to a progressive (measurable) deformity OR
   C. Objective signs/symptoms compatible with neurogenic claudication or lumbar radiculopathy that is supported by MRI or CT (with or without myelography) and by a detailed clinical neurological examination OR
   D. Evidence from a post-laminectomy structural study of either:
      1. 100% loss of facet surface area unilaterally, OR
      2. 50% combined loss of facet surface area bilaterally

IV. If conservative care has failed to relieve symptoms and the patient has had a prior fusion at the same level, lumbar fusion should be considered only if the patient has one or more of the following:
   A. Pseudarthrosis with or without hardware failure, confirmed by objective evidence of pseudarthrosis (e.g. abnormal thin slice CT scan)
   B. Neurogenic claudication supported by either MRI, CT, or myelography
   C. Lumbar radiculopathy supported by either MRI, CT, or myelography, or supported by a detailed clinical neurological or neurosurgical examination

V. If conservative care has failed to relieve symptoms and the patient has had a prior fusion at a level adjacent to the new one being considered, lumbar fusion should be considered only if the patient meets the same criteria as described for patients with no prior history of spine surgery (see above).

VI. Contraindications for lumbar fusions, even when patients meet the criteria described above.
   A. Absolute contraindications

      Lumbar fusion is not indicated with an initial laminectomy/discectomy related to unilateral compression of a lumbar nerve root.

B. Relative contraindications

1. Severe physical deconditioning
2. Current smoking
3. Multiple level degenerative disease of the lumbar spine
4. Greater than 12 months of disability (time-loss compensation benefits) prior to consideration of fusion
5. No evidence of functional recovery (return to work) for at least six months following the most recent spine surgery
6. Psychosocial factors that are correlated with poor outcome, such as:
    a. History of drug or alcohol abuse
    b. High degrees of somatization on clinical or psychological evaluation
    c. Presence of a personality disorder or major psychiatric illness
    d. Current evidence of factitious disorder

VII. When the physician wants to proceed with a lumbar fusion request:

A. The physician should be aware of the following research based findings:
    1. The chance of an injured worker no longer being disabled 2 years after lumbar fusion is only 32%.
    2. More than 50% of workers who received lumbar fusion through the Washington workers' compensation program felt that both pain and functional recovery were no better or worse after lumbar fusion.
    3. The overall rate of reoperation within 2 years for all fusions is approximately 23%.
    4. Smoking at the time of fusion greatly increases the risk of pseudarthrosis.
    5. Pain relief, even when present, is not likely to be complete.
    6. The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.

B. The operating surgeon should follow the lumbar fusion patient at least every two months for the first six postoperative months. At the six-month examination, if the patient is still experiencing significant pain, a face-to-face evaluation should be conducted, which includes all of the following elements:

    1. Neurologic examination
    2. Thin slice CT to rule out pseudarthrosis
    3. Repeat flexion/extension films to rule out instability

    If new objective neurologic signs are absent, and if there is no objective evidence of fusion failure, the patient may have reached maximum medical improvement and an impairment rating (permanent partial disability [PPD] assessment) may be appropriate.

C. Prior to lumbar fusion, clinical psychological or psychiatric assessment should be performed on all patients who meet the lumbar fusion

criteria and who have been receiving time-loss compensation benefits. This assessment is intended to help the requesting surgeon identify specific psychological risk factors for chronic disability that may be barriers to recovery following lumbar fusion.

D. All intraoperative determinations of instability that lead to fusion must be clearly documented at the time, and (if requested by the Department of Labor and Industries) subsequently discussed with a peer surgeon.

E. Although adding to the clinical database, provocative discography, diagnostic facet joint injections, and pain relief during the use of a rigid spinal brace are not definitive indications for fusion.

F. Anterior Lumbar Interbody Fusion (ALIF), if indicated, should be done only in conjunction with a posterior stabilization procedure.

Note: Prior to surgery, the physician should discuss with the patient the information provided in the form attached to the original guideline ("What You Should Know about Lumbar Fusion Surgery"). After discussing these details, both the physician and patient should sign at the bottom of the form. The form should be kept in the patient's medical records at the requesting surgeon's office.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

The recommendations were developed by combining pertinent evidence from the medical literature with the opinions of clinical expert consultants and community-based practicing physicians. Because of a paucity of specific evidence related to the injured worker population, the guideline is more heavily based on expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate medical treatment of low back pain and associated symptoms for injured workers
- Improved identification of appropriate candidates for lumbar fusion surgery
- Appropriate physician referral for lumbar fusion surgery
- Appropriate utilization review recommendations for approval or denial of lumbar fusion surgery requests
- Increased provider/patient knowledge regarding potential effect of lumbar fusion surgery on health and recovery

POTENTIAL HARMS

Physicians requesting a lumbar fusion should be aware of the following research based findings:

- The chance of an injured worker no longer being disabled 2 years after lumbar fusion is only 32%.
- More than 50% of workers who received lumbar fusion through the Washington workers' compensation program felt that both pain and functional recovery were no better or worse after lumbar fusion.
- The overall rate of reoperation within 2 years for all fusions is approximately 23%.
- Smoking at the time of fusion greatly increases the risk of pseudarthrosis.
- Pain relief, even when present, is not likely to be complete.
- The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications for lumbar fusions, even when patients meet certain defined criteria (see the "Major Recommendations" field):

- Absolute contraindications
    - Lumbar fusion is not indicated with an initial laminectomy/discectomy related to unilateral compression of a lumbar nerve root.
- Relative contraindications
    - Severe physical de-conditioning
    - Current smoking
    - Multiple level degenerative disease of the lumbar spine
    - Greater than 12 months of disability (time-loss compensation benefits) prior to consideration of fusion
    - No evidence of functional recovery (return to work) for at least six months following the most recent spine surgery
    - Psychosocial factors that are correlated with poor outcome, such as:
        - History of drug or alcohol abuse
        - High degrees of somatization on clinical or psychological evaluation
        - Presence of a personality disorder or major psychiatric illness
        - Current evidence of factitious disorder

QUALIFYING STATEMENTS

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- The Office of the Medical Director works closely with the provider community to develop medical treatment guidelines on a wide range of topics relevant to injured workers. Guidelines cover areas such as lumbar fusion, indications for lumbar magnetic resonance imaging (MRI), and the prescribing of controlled substances. Although doctors are expected to be familiar with the guidelines

and follow the recommendations, the department also understands that guidelines are not hard-and-fast rules. Good medical judgment is important in deciding how to use and interpret this information.

- The guideline is meant to be a gold standard for the majority of requests, but for the minority of workers who appear to fall outside of the guideline and whose complexity of clinical findings exceeds the specificity of the guideline, a further review by a specialty-matched physician is conducted.
- The guideline-setting process will be iterative; that is, although initial guidelines may be quite liberally constructed, subsequent tightening of the guideline would occur as other national guidelines are set, or other scientific evidence (e.g., from outcomes research) becomes available. This iterative process stands in contrast to the method in some states of placing guidelines in regulation. Although such regulation could aid in the dissemination and quality oversight of guidelines, flexibility in creating updated guidelines might be limited.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

All of the surgical guidelines established by the Department of Labor and Industries in collaboration with the Washington State Medical Association (WSMA) have been implemented in the context of the Utilization Review (UR) program (complete details regarding the Utilization Review program can be found on the Washington State Department of Labor and Industries Web site). It has been critical in contract negotiations with UR vendors to specify that the vendor is willing to substitute WSMA-generated guidelines for less specific standards already in use by the company. The Department of Labor and Industries initiated an outpatient UR program, and this has allowed full implementation of guidelines related to outpatient procedures (e.g., carpal tunnel surgery, magnetic resonance imagings [MRIs]). The scheduled drug use guideline has been used internally, but has not been formally implemented in a UR program.

The intention of the joint Department of Labor and Industries and WSMA Medical Guidelines Subcommittee was to develop treatment guidelines that would be implemented in a nonadversarial way. The subcommittee tried to distinguish between clear-cut indications for procedures and indications that were questionable. The expectation was that when surgery was requested for a patient with clear-cut indications, the request would be approved by nurse reviewers. However, if such clear-cut indications were not present, the request would not be automatically denied. Instead, it would be referred to a physician consultant who would review the patient's file, discuss the case with the requesting surgeon, and make recommendations to the claims manager.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Guidelines for lumbar fusion (arthrodesis). Olympia (WA): Washington State Department of Labor and Industries; 2002 Aug. 5 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun (republished 2002 Aug)

GUIDELINE DEVELOPER(S)

Washington State Department of Labor and Industries - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

Washington State Department of Labor and Industries

GUIDELINE COMMITTEE

Washington State Department of Labor and Industries (L&I), Washington State Medical Association (WSMA) Industrial Insurance Advisory Section of the Interspecialty Council

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Medical Director, Washington State Department of Labor and Industries (L&I): Gary Franklin, MD

The individual names of the Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee are not provided in the original guideline document.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Washington State Department of Labor and Industries. Guidelines for lumbar fusion (arthrodesis). Olympia (WA): Washington State Department of Labor and Industries; 1999 Jun. 5 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Washington State Department of Labor and Industries Web site.

Print copies: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

AVAILABILITY OF COMPANION DOCUMENTS

This guideline is one of 16 guidelines published in the following monograph:

- Medical treatment guidelines. Olympia (WA): Washington State Department of Labor and Industries, 2002 Aug. 109 p.

Also included in this monograph:

- Grannemann TW (editor). Review, regulate, or reform? What works to control workers' compensation medical costs? In: Medical treatment guidelines. Olympia (WA): Washington State Department of Labor and Industries, 1994 (republished 2002). p. 3-19.

Electronic copies: Available from the Washington State Department of Labor and Industries Web site.

The following is also available:

- Washington State Department of Labor and Industries. Utilization Review Program. New UR Firm. (Provider Bulletin: PB 02-04). Olympia (WA): Washington State Department of Labor and Industries; 2002 Apr. 12 p.

Print copies are available from the L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

PATIENT RESOURCES

The following is available:

- What you should know about lumbar fusion surgery. In: Guidelines for lumbar fusion (arthrodesis). Olympia (WA): Washington State Department of Labor and Industries, 2002.

Print copies are available from the L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

NGC STATUS

This summary was completed by ECRI on July 24, 1999. The information was verified by the guideline developer on October 17, 1999. This summary was updated by ECRI on December 20, 2002. The information was verified by the guideline developer on December 31, 2002. This summary was updated by ECRI on May 27, 2004. The information was verified by the guideline developer on June 14, 2004.

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